MEDICARE MANAGED CARE NATIONAL MARKETING GUIDE

Revised June 2000

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Chapter 1 -- Introduction

The National Marketing Guide ("the Guide") is provided as a supplement to the marketing chapter of the Medicare Managed Care Manual (previously known as the Medicare Health Maintenance Organization/Competitive Medical Plan (HMO/CMP) Manual) and marketing review policy updates provided in Operational Policy Letters (OPLs).[1] The Guide is intended to 1) expedite the process for HCFA's review of marketing materials; 2) conserve resources by avoiding multiple submissions/reviews of a document prior to final approval; 3) ensure consistent marketing review across the nation; and, most importantly 4) enable managed care organizations to develop accurate, consumer-friendly, managed care marketing information that will assist them in making informed health care choices.[2] The Guide is not an all-inclusive, static document, but instead represents a "snapshot" of HCFA's required marketing practices and policies. The Guide will be updated on a regular basis to include all OPLs and other instructions pertaining to the review of marketing materials.

Marketing materials are defined to include any informational material targeted to Medicare beneficiaries that promotes the M+C organization or any M+C plan offered by the M+C Organization or explains how Medicare services are covered under an M+C plan.[3] (See 42 CFR 422.80(b)). The definition of marketing materials extends beyond the public's general conception of advertising materials to include notification forms and letters used to enroll, disenroll, and communicate with the member on many different membership scenarios. General guidance regarding the marketing review process, including the process for review of materials submitted by national organizations, is provided in Chapter 2. In addition, the Guide contains two separate chapters devoted to the discussion of guidelines for marketing materials; Chapter 3 addresses requirements for advertising or "pre-enrollment" materials and Chapter 4 addresses requirements for beneficiary notification materials that are provided for beneficiaries currently enrolled in the plan. Promotional activities, including health fairs and sales presentations, are also included in the definition of marketing materials and are discussed in Chapter 5.

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[1] Compliance with HCFA marketing policy as outlined in regulations at 42 CFR 422.80, the Medicare Managed Care Manual, and other operational instructions found outside the National Marketing Guide remains a requirement for participation in the Medicare managed care program and Medicare+Choice program.

[2] The primary HCFA/health plan contractual frame of reference in the Guide is a coordinated care plan contracting under the Medicare+Choice program. Where applicable, alternative language is provided for cost contractors as well as scenarios involving the point-of-service (POS) and Visitor Program features which may be applicable for M+C and/or cost contractors.

[3] These guidelines apply to Medicare+Choice Organizations (M+COs) as well as ' 1876 cost contractors. Therefore, for ease of review and reference, the term Ahealth plan@ is used throughout this document to include requirements specific to ' 1876 cost contractors.

Chapter 2 -- Marketing Review Process

Marketing review consists of 1) pre-approval of marketing materials before they are used by the health plan/M+CO; 2) review of on-site marketing facilities, products, and activities during regularly scheduled contract compliance monitoring visits; 3) random review of actual marketing pieces as they are used in/by the media; and 4) "for cause" review of materials and activities when complaints are made by any source. The Guide deals primarily with the pre-approval of marketing materials. As outlined in regulations at 42 CFR 422.80(a) and the Medicare Managed Care Manual, M+COs may not distribute any marketing materials or election forms to individuals eligible to elect an M+C plan unless such materials have been submitted to HCFA at least 45 days prior to distribution and HCFA has not disapproved the materials. There is a limited exception to this requirement for model beneficiary notices, as outlined in Chapter 4, Section 1 of this Guide. Guidelines for HCFA review are further described at 42 CFR 422.80(c). Marketing materials, once approved, remain approved until either the piece is changed by the M+CO or conditions change such that the material is no longer accurate. HCFA may, at any time, require an M+CO to change any previously approved marketing materials if found to be inaccurate, even if the original submission was accurate at the time.

Section 1 of this chapter describes the marketing review process for materials produced by national ("chain") organizations. Section 2 outlines the requirements for M+COs that would like to attain "use and file" status with respect to their advertising (pre-enrollment) materials.

Section 1 -- Marketing Review Process for National Organizations

HCFA established specific guidelines for the review of marketing materials submitted by a national ("chain") organization that offers M+C plans in more than one region of the country in OPL 97.060, "Updating of the National Marketing Guide," dated July 17, 1998. The guidelines apply both to marketing materials submitted with new applications as well as post-contract marketing efforts and are intended to 1) streamline the marketing process for national organizations; 2) avoid unnecessary repetition of document submission and review; and 3) decrease the amount of time currently being spent on marketing material review.

Under the review process for national ("chain") organizations, the lead Regional Office (RO) reviews and approves materials identified by the organization for use in more than one HCFA region of the country. This material is identified by MCOs as "national plan material." The local RO reviews materials that are applicable to the local plan(s) only, usually described as "local material."[4] Organizations may also submit "hybrid" marketing material that is a combination of national information applicable to all plans and local information specific to each plan. The local information typically pertains to the plan's provider network, accessibility issues, or the benefits offered by a specific plan. In these situations, the lead and local ROs

[4] Approval letters for these materials will state that the material is approved for local use only.

independently review and approve separate parts of the material; the lead RO reviews and approves the national information in the piece of marketing material, while the local RO reviews and approves the information specific to a particular plan in the region. The lead and local ROs communicate separately to the organization with respect to the approval or denial and resubmission of the materials.

Generally the lead RO is the Region where the organization's corporate office is located.[5] The local RO is one with at least one of the organization's contracted plans in its Region. Staff from the local ROs, lead RO, CO plan manager, and the CO financial reviewer for each organization comprise the national plan team for that organization.

The lead RO is responsible for notifying the local ROs of the approval date for national materials and refers policy issues that require additional development or clarification to the appropriate Central Office (CO) component. The lead RO may request assistance from the Marketing Product Consistency Team (PCT) or CO managers, as necessary.[6] The lead RO also determines Use and File status (described later in this Chapter) for national plan material, while the local RO determines Use and File status for local material.

The M+CO has the following responsibilities with respect to the submission of national and local marketing materials:

- Ensure materials submitted are consistent with the requirements in the Guide and the Medicare Managed Care Manual.

- Submit for review and approval proposed copies of its national marketing materials to the lead RO with a dated cover letter which identifies the material as national. (Note: All submitted materials, both national and local, must be identified with a sequential identification code. The identifying system will be determined by the RO "national plan team.")

- Submit for review and approval proposed copies of local marketing materials to the local RO with a dated cover letter. This material will be reviewed and approved by the local RO for local use only.

- Identify marketing materials that contain both national and local information as "hybrid" materials and submit for review and approval proposed copies to the lead RO and local RO.

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[5] In some situations, a lead RO may not be the one in which the plan=s corporate office is located. For example, if the plan=s corporate headquarters is in a region with no Medicare contracts, the national plan team designates another lead RO or the corporate office location changes. Authority for determination of lead RO assignments resides with RO officials representing the geographic locations of the national plan headquarters and contract sites. When necessary, appropriate RO consortia administrators will assist in lead RO determinations.

[6] The Marketing PCT is comprised of representatives from all ten HCFA ROs and meets monthly to discuss and resolve issues involving consistencies in the interpretation, application, and approval of marketing materials.

- Identify previously approved local material that the plan now wants to use nationally and submit it to the lead RO for review and approval. Such materials must be accompanied by the local RO's original approval letter/documentation.

- Distribute final copies of its national marketing materials, within a time frame to be determined by its national plan team (10 days after HCFA approval is recommended), to the lead and local ROs with a dated cover letter which identifies the recipients. (Note: Although the local ROs no longer play a part in approval of the national marketing piece, the health plan/M+CO must send a final copy of the approved material to the local ROs for their records.)

Section 2 -- Requirements for Use and File Status

The Use and File system is designed to streamline the marketing materials and activities review process. Under this process, health plans/M+COs that can prove to HCFA that they can continually meet a particular standard of performance will be able to publish and distribute certain marketing materials without prior HCFA approval. The Use and File system has several advantages -- it is a time saver for both HCFA and health plans/M+COs, and health plans/M+COs can schedule their publication of advertising without waiting for HCFA approval.

This section outlines the criteria for initial and ongoing eligibility for the Use and File system, HCFA's tracking of Use and File status, and recommendations for obtaining Use and File status.

Use and File Definitions

Eligible Material: All advertising/pre-enrollment material used to market the health plan to non-members and all membership retention materials (i.e. member handbooks, etc.), with the exception of benefit documents, e.g., the Summary of Benefits.

Materials that are **not** eligible for the Use and File system include beneficiary notification materials (post-enrollment materials) or those materials that describe membership rules and benefits, such as: the Evidence of Coverage, Member Handbook, Summary of Benefits, and Member Notices (such as the Annual Notice of Change, Enrollment/Disenrollment-related materials and notices, provider termination notices, claims denial notices etc.).

ACCEPTABLE: All material that is correct as written, or, if it needs modification, the changes requested are minimal and/or could have been approved without revision. In other words, there are no phrases or terms used that are listed in the Must Use/Can't Use/Can Use Chart (see Chapter 3) that fall under the category of "Can't Use." Likewise, there are no phrases or terms listed under "Must Use" for the particular marketing material type that are omitted from the material. In addition, materials generally must not appear misleading and clearly represent the plan's product as well as the Medicare program.

NOT ACCEPTABLE: All material that does not meet the definition of "ACCEPTABLE." This would include material that is misleading, incorrect, or is contrary to what is specifically delineated in this Guide.

Eligibility for the Use and File System

To become eligible for the Use and File System, a health plan/M+CO must submit marketing material that meets the following criteria[7]:

1. Ninety-five (95) percent of materials submitted during the preceding quarter were approved without major revisions requested by HCFA ("ACCEPTABLE" per Use and File criteria).

2. The health plan/M+CO needs to demonstrate that it has a solid understanding of HCFA marketing criteria in a number of marketing pieces, demonstrated by a minimum of 10 eligible pieces in a quarter.

3. The HCFA Regional Office Managed Care Specialist assigned to the health plan/M+CO must give approval.

4. The health plan/M+CO must have been in the program for at least 18 months.

Criteria for Continuation of Use and File Status

1. The health plan/M+CO must provide HCFA with copies of all printed materials within 10 days of their use. Health plans/M+COs must specify date of initial distribution or publication when filing materials with HCFA.

2. The health plan/M+CO must continue to submit to HCFA for review at least 45 days prior to planned distribution all other materials that are not eligible for the Use and File system. (For clarification, see the definition of "Eligible Material" above.)

3. Health plans/M+COs may lose approval to use the Use and File procedure if they use misleading or incomplete materials discovered through complaints or spot checks or they fail to file materials within 10 days after distribution or publication.

4. Health plans/M+COs that would like to use this procedure must agree to retract and revise materials which are found to be misleading or incomplete.

5. Health plans/M+COs that have Use and File privileges may still submit for prior approval any materials ("Eligible Materials") on which they would like guidance from HCFA. This will prevent health plans/M+COs from losing Use and File privileges for using misleading or incomplete materials, as explained in Item 3 above.

[7]Health plans converting from cost to M+C contracts with a total of 18 months experience and an acceptable marketing history can qualify for Use and File.

Recommendations for Obtaining Use and File Status

1. Health plans/M+COs should share these marketing guidelines with their staff as well as contracted advertising agency staff who are involved in the development of marketing materials related to the Medicare product. It is also a good idea to have a central contact person who is familiar with the Guide give materials a final review before sending them on to HCFA to ensure that Use and File criteria are met.

2. Health plans/M+COs should carefully review marketing materials that are deemed by HCFA not to meet Use and File criteria to determine trends. Sometimes there are recurring patterns of mistakes. Health plans/M+COs should also review comments by HCFA reviewers on materials and incorporate changes into subsequent submissions.

3. One place where mistakes frequently occur is the disclaimer language. Health plans/M+COs should submit the specific disclaimer language that will be used in marketing materials to HCFA for review and approval.

Operational Considerations--Questions and Answers

1. Q What if a health plan/M+CO has Use and File status at the regional level and the national level does not, or vice versa (multi-site, chain organizations)?

A Multi-site companies can maintain Use and File status for individual contracting entities as well as for all contracted entities. The Use and File status of a single company and any multi-site entities are independent of each other. Individual companies can maintain this status when multi-site entities do not. In addition, a multi-site company can have Use and File status when individual companies do not.

Use and File status for individual companies is maintained by the region which is responsible for monitoring the company's contract. Multi-site Use and File status is maintained by the lead region.

2. **Q** For quarterly accounting purposes, is a piece of marketing material submitted for Use and File status determination counted for the quarter in which the document is submitted to HCFA or in the quarter when HCFA sends the response letter back to the health plan/M+CO?

A It is counted according to the date it is submitted to HCFA for review. The date on the submission document is the determining date.

3. **Q** Should the failure to submit required supporting documentation (e.g., survey results, newspaper articles, etc.) for a marketing piece, along with the initial request for review of the primary document, result in a “Not Acceptable” determination?

A Failure to submit support documentation should not result in a "Not Acceptable" finding. Instead, the date of submission should be changed to the date when all materials are received and are ready for review. This means if a health plan/M+CO fails to submit a survey that belongs to a marketing piece, HCFA should inform the health plan about the omission of the additional material and, when it arrives, consider this date the submission date for the Use and File period.

4. **Q** Sometimes health plans/M+COs revise and re-submit a piece that was originally rejected by HCFA. If HCFA determines that the piece meets approval on the basis of Use and File criteria the second time around, will that piece be counted in the tally for gaining approval for use of the Use and File procedure?

A No. HCFA will not count materials for the tally to meet Use and File status if the health plan materials conform only after HCFA review and comment. Such a policy would result in health plans/M+COs with little understanding and inadequate knowledge of HCFA marketing principles to obtain Use and File status. Under such a policy, a health plan/M+COs could submit substandard materials 10 times and still qualify for Use and File status. This would clearly undercut the "marketing quality" intent that HCFA associates with Use and File status.

Chapter 3 -- Guidelines for Advertising Materials

Section 1 -- Guidelines for Advertising (Pre-enrollment) Materials

This section provides guidance to health plans/M+COs regarding sales packages and language that may be used in marketing materials. Advertising/pre-enrollment material may be defined as that material that is used to market the health plan to non-members and all membership retention materials. This includes all ads (print as well as radio and TV ads) and certain other material such as sales scripts, sales presentation flyers, and direct mail pieces. This chapter offers a general guide and a matrix describing marketing language that health plans/M+COs "Must Use/Can't Use/Can Use."

These guidelines were created by identifying language frequently omitted by health plans/M+COs or revised by HCFA. Acceptable language was created to meet both HCFA requirements and the needs of the health plan/M+CO. Although use of suggested language is not required, we strongly recommend its use as a means of expediting the review process and of achieving greater consistency among marketing materials. Please note that the specific language and format used in standardized marketing materials like the standardized Summary of Benefits (SB) is required. Please also note that the language provided in the "Must Use" column of the "Must Use/Can Use/Can't Use Chart" (see Section 3 of this Chapter) is required verbatim for the marketing materials as specified in the chart.

It should be evident that some phrases may or may not apply to your health plan's/M+CO's benefit package or marketing strategy. We caution you to apply the information contained in this document with the understanding that it must be evaluated for applicability to your health plan/M+CO.

Listed below are certain informational items and phrases that are frequently omitted in materials submitted to HCFA for review, but must be present in marketing materials in order for approval to be granted.

- For M+C coordinated care plans, the concept of "lock-in" must be clearly explained in all materials. For marketing pieces which tend to be of short duration we suggest: "You must receive all routine care from <name of plan/M+CO> plan providers" or "You must use <name of plan/M+CO> plan providers except in emergent or urgent care situations or for out-of-are renal dialysis." However, in all written materials used to make a sale, a more expanded version is suggested: "If you obtain routine care from out-of-plan providers neither Medicare nor the health plan/M+CO will be responsible for the costs." Modify materials if the health plan has a Point-of-Service (POS) or Visitors' Program benefit or is a cost contractor or Private Fee-For-Service Plan.

- All marketing materials must clearly explain the concept of networks and sub-networks and the process for obtaining services including referral requirements.

- All marketing materials must include a statement that the health plan/M+CO contracts with the Federal government. One possible statement is "A Federally Qualified HMO with a Medicare contract." Cost-contractors may use "An HMO with a Medicare contract" and/or "An M+CO with a Medicare contract" if they are state licensed as HMOs. Medicare+Choice organizations may identify Medicare products as "An HMO with an Medicare+Choice contract" if they are Federally Qualified or state licensed as HMOs. M+COs may also identify their Medicare plans as "An M+CO with an Medicare+Choice contract," or "A Coordinated Care Plan with an Medicare+Choice contract," if the health plan/M+CO meets the requirements of section 1851(a)(2)(A) of the Act. In addition, an M+CO may describe its Medicare product as a "Medicare+Choice plan offered by [name of M+CO], a Medicare+Choice Organization".

  A M+CO may only identify itself as an "M+C PSO" or imply that it is one of the PSO options for Medicare beneficiaries under M+C if it has received a State licensure waiver from HCFA in accordance with 42 CFR 422.370-.378. State licensed M+COs may identify themselves in marketing materials as a "Provider Sponsored Organization (PSO)," a "State licensed PSO with a M+C contract," or any other term generally applied to managed care organizations that are sponsored by health care providers as long as they do not use the specific term "M+C PSO" or imply that they are one of the specific PSO options for Medicare beneficiaries defined by the Balanced Budget Act of 1997 and implementing regulations at 42 CFR 422.350-.356.

- M+COs are permitted to use ethnic and religious affiliation in their plan names, as long as the legal entity to which the plan belongs has a similar proper name/affiliation. For instance, if a plan is affiliated with the Swedish Hospital of Minnesota, it would be permissible for the plan to use the tag line, "Swedish Plan, offered by Swedish Hospital System of Minnesota."

- Beneficiaries with disabilities must be considered part of the audience that any marketing strategy is intended to reach. Specifically for those health plans/M+COs using the term "senior" in their product name, reference must be made to the availability of the Medicare product to beneficiaries with disabilities. (See items 1 and 2 under Eligibility Clarification.) It is HCFA's intention, upon publication of the final M+C regulation, to prohibit all M+COs from using the term "senior" or "65+" in plan names. This will be further explained in the final rule, along with a provision for "grandfathering" in those health plans/M+COs that are currently in the program and whose names contain either "senior" or "65+".

- Readability of written materials is crucial to informed choice for Medicare beneficiaries. All member materials that convey the rights and responsibilities of the health plan/M+CO and the member must be printed with a 12-point font size or larger. Materials include, but are not limited to, the Evidence of Coverage (EOC) or member contract, the enrollment and disenrollment applications, letters confirming enrollment and disenrollment, notices of non-coverage (NONC) and notices informing members of their right to an appeals process. HCFA is cognizant of the fact that when actually measured font size 12 point may vary with

the result that some font types may be smaller than others. Times New Roman font type is the standard by which font size is measured. Therefore, if M+COs choose to use a different font type, it is their responsibility to ensure that the font used is equivalent to or larger than Times New Roman 12 point.

- The 12-point font size or larger rule also applies to any footnotes or subscript annotations in notices. In all non-notice material (e.g., TV advertisements) the footnote must be the same size font as the commercial message. The term "commercial message" refers to the content of the material which is designed to capture the reader's attention regarding membership in the health plan/M+CO. The term does NOT refer to the commercial membership (i.e., non Medicare/Medicaid members) of the health plan/M+CO. All non-notice materials must have the same font size for both the commercial message and footnotes. The size is left to the discretion of the health plan/M+CO and can be smaller than size 12 font, but the commercial message and footnotes must be the same size font.

- Health plans/M+COs must adopt a standard procedure for footnote placement. Footnotes should appear either at the end of the document or the bottom of each page and in the same place throughout the document. In other words, for example, the health plan/M+CO cannot include a footnote at the bottom of page 2 and then reference this footnote on page 8; the footnote has to also appear at the bottom of page 8.

- Health plans/M+COs must list the hours of operation for customer services and other health plan services anywhere that these phone numbers are provided. This requirement does not apply to any numbers included on advertising materials for persons to call for more information.

- TDD/TTY numbers must appear in conjunction with any other phone numbers in the same font size and style, along with the hours of operation, if these are also provided with the plan phone numbers. This is required for all media. Health plans/M+COs can use either their own or state relay services, as long as the number is included.

- Definition of Outdoor Advertising (ODA)-- ODA is used to capture the quick attention of a mobile audience passing the outdoor display (e.g., billboards, signs attached to transportation vehicles, etc.). ODA is designed to catch the attention of a person and influence them to call for detailed information on the product being advertised. Due to the nature of ODA, HCFA is willing to waive the disclaimer information required with other forms of marketing media (e.g., lock-in and premium information).[8]

- For "1876 cost-contracting health plans only - In all marketing materials (e.g., brochure narratives and introductions to side-by-side comparisons) the health plan must indicate that it meets Medicare regulatory requirements for providing enrollment opportunity and benefit

[8] See Section 3 of this Chapter for specific application requirements for ODA.

packages for both Part A and B and Part B-only eligible beneficiaries.[9]

- Where M+COs may file separate/distinct ACRs and PBPs covering the same service area (or portions of the same service area), there is no requirement that all plans be identified in all of the health plan's/M+CO's marketing materials, although M+COs may do so at their discretion. MCOs must disclose whether other plans are available in their Annual Notice of Change letter.

- Cost-contracting health plans must market a low option or basic benefit package that is identical to the Medicare fee-for-service benefit package (except for any additional benefits the health plan may offer at no charge, for which the health plan claims no reimbursement). Information on the availability of this package must appear in all of the health plan's marketing materials. The health plan/M+CO may also offer additional optional enriched benefit packages for an additional charge to the extent they wish.

- Health plans/M+COs may not use Medicare member lists for non-plan-specific purposes. If a health plan/M+CO has questions regarding specific material which it wishes to send to its Medicare members, the material should be submitted to HCFA for a decision.

- Marketing material identification systems: Health plans/M+COs must use the system mandated by the reviewing RO for identifying marketing materials submitted to HCFA. If the reviewing RO does not have a system, health plans/M+COs may use their own system for identifying marketing materials. The health plan identifier should appear on the lower left or right side of the marketing piece. After the RO approves the marketing piece, the approval date (month/year) should always be posted to the marketing piece. The approval date is the date the health plan/M+CO receives the approved marketing piece back from HCFA.

- Review of marketing materials in non-English language or Braille: For marketing with non-English or Braille materials the health plan/M+CO must submit the non-English or Braille version of the marketing piece, an English version (translation) of the piece, and a letter of attestation from the health plan/M+CO that both pieces convey the same information. Health plans/M+COs will be subject to verification monitoring review and associated penalties for violation of this HCFA policy. If national health plans/M+COs have submitted materials in English to the lead Regional Office and these have been approved, the same materials in other languages or Braille may be used provided that health plans/M+COs submit attestation letters vouching that the non-English or Braille version contains the same information as the English language version.

- Marketing through the Internet: HCFA considers the Internet as simply another vehicle for the distribution of marketing information. Therefore, all regulatory rules and requirements associated with all other marketing conveyances (e.g., newspaper, radio, TV, brochures, etc.) are applicable to health plan/M+CO marketing activity on the Internet. HCFA marketing

[9]Under M+C, individuals who are not already members - those that are Agrandfathered@ in - must have both Parts A and B of Medicare in order to be eligible for enrollment.

review authority extends to all marketing activity (both advertising and beneficiary notification activity) the health plan/M+CO pursues via the Internet.

- Health education materials are generally not under the purview of HCFA marketing review. However, if such materials are used in any way to promote the M+CO or explain benefits, then they are considered marketing materials and must be approved before use. If there is any "commercial message" (defined previously in this section) or beneficiary notification information in a health education piece, it must be reviewed by HCFA.

- M+COs may refer to results of studies or statistical data in relation to customer satisfaction, quality, etc. as long as specific study details are given (at a minimum source, dates, sample size, number of plans surveyed). M+COs may not use study or statistical data to directly compare their plan to another. If M+COs use study data that includes information on several other M+COs, they will not be required to include data on all organizations. However, study details, such as the number of plans included, must be disclosed. Qualified superlatives (e.g. among the best, one of the highest ranked, etc.) may be used. Superlatives (e.g. ranked number one, etc.) may only be used if they are substantiated with supporting data.

- Sales scripts, both for in-home and telephone sales use, must be reviewed by HCFA prior to use. However, health plans/M+COs are not required to adhere to a specific format for submission (i.e. verbatim text or bullet points).

- HCFA recognizes the difference of purpose and intent between company logos/product tag lines and other advertising marketing materials. The guidelines regarding the use of unsubstantiated statements that apply to advertising materials **do not** apply to logos/taglines. Contracting health plans will be allowed to use unsubstantiated "mission statement" type terminology on their logos and in their product tag lines (e.g. "Your health is our major concern", "Quality care is our pledge to you," "First Care means quality care," etc.). This latitude is allowed **only in logo/product tag line language.** Such unsubstantiated claims cannot be used in general advertising text regardless of the communication media employed to distribute the message. The use of superlatives **is not permitted** in logos/product tag lines (e.g, "First Care means the first in quality care" or "Senior's Plus means the best in managed care"). Refer to the Must Use/Can't Use/Can Use chart in Section 3 of this Chapter for full information on restrictions associated with the use of superlatives.

- M+C organizations may market plans directly to beneficiaries of former Medicare plans that have chosen not to renew their contracts as long as the following requirements are met:

    1) No such marketing is permitted until after the date the beneficiary has received the plan termination letter; and

    2) In addition to the targeted message, the marketing piece must contain a statement indicating that the plan is open to **all** Medicare beneficiaries eligible by age or disability in the plan's service area.

Section 2 -- Sales Package Minimum Information Requirements

This section contains guidance regarding rules that health plans/M+COs are required to provide in writing to beneficiaries prior to enrollment.

Eligibility Requirements

- A health plan/M+CO cannot health screen its membership, with the exception of asking for information on End Stage Renal Disease (ESRD, or kidney failure) status. This exception is allowed since Federal law will not allow the health plan/M+CO to enroll people with (ESRD). For the purposes of Medicare managed care eligibility, ESRD is that stage of kidney impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life. Individuals who have received a successful kidney transplant and no longer require regular kidney dialysis or a transplant to maintain life are not medically determined to have ESRD. Currently-enrolled individuals who become Medicare eligible and who have ESRD can retain their membership at the time they convert to Medicare.

- Members must have Medicare Parts A and B to enroll in the M+CO. For prospective members who do not have Medicare Part A coverage, the M+CO may tell the inquiring individual that they can purchase Part A coverage from the Social Security Administration. In all cases, members must continue to pay the Medicare Part B premium once enrolled in the health plan/M+CO. M+COs that converted from section 1876 contracts (January 1999) must continue to provide coverage for individuals with Part B only who were "grandfathered" into an M+C plan. For these grand fathered members only, payment of an additional Part A premium (per the approved ACR/PBP) to the M+CO is permitted.

- Health plans/M+COs must be available to all Medicare eligible applicants who live in the service area of the health plan/M+CO. The health plan/M+CO must designate the service area in the sales material in terms of counties or zip codes. If a prospective member does not live in the service area, the health plan/M+CO need not accept the member's application. It is permissible for health plans/M+COs to have separate marketing brochures for each geographic region in the service area so that all zip codes for the entire service area do not have to appear in all marketing brochures.

Enrollment

- When completing an application, a beneficiary must:

    1. Sign and date the application.
    2. Put his/her Medicare number on the application as it appears on his/her red, white, and blue Medicare card.

- State that the health plan/M+CO will notify the member when his/her enrollment is

effective. if and when their enrollment is effective. Refer to section 3.5 of OPL 99.100 and OPL 2000.113 for information on enrollment effective dates.

- State that once a person enrolls with the health plan/M+CO, s/he will receive a health plan/M+CO card (if applicable). This card must be used when receiving all health care services.

- State that the health plan/M+CO cannot enroll anyone in the health plan/M+CO who has ESRD. For the purposes of Medicare managed care eligibility, ESRD is that stage of kidney impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life. Individuals who have received a successful kidney transplant and no longer require regular kidney dialysis or a transplant to maintain life are not medically determined to have ESRD. Currently-enrolled individuals who become Medicare-eligible and who have ESRD can retain their membership at the time they convert to Medicare.

- State that Medigap insurance or other supplemental insurance is no longer necessary because the health plan/M+CO pays for deductibles and coinsurance usually covered by Medigap. However, if the member has a Medigap policy and decides to enroll in a health plan/M+CO, they may either keep the policy or they may cancel it if they decide they wish to remain in the health plan/M+CO. The member will generally not need a Medigap policy if they enroll in a Medicare-contracting health plan/M+CO.

- State that a Medigap policy could be of value to the member if they leave a health plan/M+CO and returned to FFS Medicare. If the member drops his/her Medigap policy upon joining the health plan/M+CO, or never had a Medigap policy, s/he might not be able to buy the policy of their choice after they have been a member of the health plan/M+CO for 12 months or more, especially if they have a health problem.

  Before the member gives up their Medigap policy, or allows a Medigap open enrollment period to expire, the member should consider discussing their particular circumstances with their State Health Insurance Assistance Program (SHIP) offices. A listing of these offices is available via the 1-800-MEDICARE helpline or the www.medicare.gov website. The services are free.

  The counseling offices also have free copies of *"The Guide to Health Insurance for People with Medicare."*

Disenrollment

- A disenrollment request must be made in writing to the health plan/M+CO, the Social Security Administration, or the Railroad Retirement Board. Members may also disenroll by joining another Medicare health plan/M+CO or by calling 1-800-MEDICARE.

- Beginning January 1, 2000, all completed Open Enrollment Period elections (i.e., enrollments *and* disenrollments) made on or before the 10th day of the month are effective the first day of the first calendar month following the date the election is made, and all Open Enrollment Period elections made after the 10th day of each month are effective the first day of the second calendar month after the election is made. Refer to OPL 2000.113 for additional information. Refer to section 3.6 of OPL 99.100 for disenrollment effective dates for the Annual Election Period and Special Election Periods.

- Members can be involuntarily disenrolled for: 1) failure to pay health plan/M+CO basic and supplementary premium; 2) a permanent move outside the geographic service area of the health plan/M+CO; 3) fraud; and/or 4) disruptive behavior.

Lock-in Requirements/Selecting a Primary Care Physician -- How to Access Care in an HMO)

Health plans/M+COs must describe rules for receipt of primary care, specialty care, hospital care, and other medical services. These rules may vary by health plan/M+CO. Health plans/M+COs must disclose specific rules for referrals for follow-up specialty care. Prior to enrollment, prospective members must be able to obtain information regarding the health plan network coverage and rules in sufficient detail to make an informed choice.

- When a beneficiary enrolls in a plan/M+CO, he/she agrees to use the network of physicians, hospitals, and providers that are affiliated with the plan for all health care services, except emergencies, urgently needed care, or out-of-area renal dialysis services.

- Contractors with a POS benefit or Visitors Program benefit should list plan-specific requirements and level of coverage found in your EOC.

- For 1876 Cost Contractors: After your enrollment is effective, in order for <name of plan/M+CO> to fully pay for medical services for you, these services (except for emergency, urgently-needed services, and out-of-area renal dialysis services) must be provided or arranged by <name of plan/M+CO>. You may receive services that are not provided or arranged by <name of plan/M+CO>, but you will be responsible for payment of all Medicare deductibles and coinsurance as well as any additional charges as prescribed by the Medicare Program. You may be liable for any charges not covered by the Medicare Program.[10]

- A plan member selects a primary care physician (PCP) to coordinate all of the member's care. A primary care physician is usually a family practitioner, general practitioner, or internist. The primary care physician knows the plan's network and can guide the member to plan specialists when needed. The member always has the option to change to a

[10] The health plan/M+CO must be sure to offer adequate explanation of Medicare card use with out-of-plan utilization that is not an emergency or an urgently-needed service.

different primary care physician. Changes in PCP will be effective according to the plan guidelines that, in some instances, could be the first or the 15th day of the following month as opposed to immediately.

- Neither the health plan/M+CO nor Medicare will pay for medical services that the member receives outside of the network unless it was authorized, or it is an emergency, urgently-needed care, or out-of-area dialysis service. The member may be responsible for paying the bill.

Emergency Care

- Members are not required to go to health plan-affiliated hospitals and practitioners when they experience an emergency. Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

  1) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child; or
  2) Serious impairment to bodily functions; or
  3) Serious dysfunction of any bodily organ or part.

  Once initiated, the services continue to be considered emergency services as long as transfer of the enrollee to the health plan/M+CO source of health care or authorized alternative is precluded because of risk to the enrollee's health or because transfer would be unreasonable given the distance and the nature of the medical condition.

- Describe precisely where emergency coverage will be available under the health plan/M+CO (e.g., the United States and its Territories, worldwide, etc.).

Urgent Care

- Urgently needed services means covered services provided when an enrollee is temporarily absent from the M+C plan's service area (or, if applicable, continuation) area (or, under unusual and extraordinary circumstances, provided when the enrollee is in the service or continuation area but the organization's provider network is temporarily unavailable or inaccessible) when such services are medically necessary and immediately required:

  1) As a result of an unforseen illness, injury, or condition; and
  2) It was not reasonable given the circumstances to obtain the services through the organization offering the M+C plan.

- Urgently-needed care provided by non-plan providers is covered when a member is in the

service area or continuation area under the unusual circumstance that the organization's provider network is temporarily unavailable or inaccessible. Normally, if a member needs urgent care and is in the health plan's/M+CO's service area or continuation area, the member is expected to obtain care from the health plan's/M+CO's providers.

Appeal Rights

- Members have a right to appeal any decision the health plan/M+CO makes regarding, but not limited to, a denial, termination, payment, or reduction of services. This includes denial of service after the service has been rendered (post-service) or denial of service prior to the service being rendered (pre-service).

Benefits and Plan Premium Information

- Premium information must include the statement: "You must continue to pay your Medicare Part B premium."

- When specifying benefits, annual limits (e.g., $1,000 annual maximum for prescription drugs), annual benefit payout (e.g., $700 for eyeglasses every 2 years) and applicable copayments (e.g., $5 copayment for a doctor visit) must be specified. Major exclusions and limitations must be stated clearly. For example, restriction of pharmacy benefits to a specific formulary or a restricted set of pharmacies must be explained. Health plans/M+COs must state clearly all monetary limits, as well as any restrictive policies which might impact a beneficiary's access to drugs or services. When annual dollar amounts or limits are provided, the health plan/M+CO must also mention the applicable quarterly or monthly limits and whether any unused portion of that benefit can be carried over from one calendar quarter to the next. Include a closing statement such as: "For full information on <plan/M+CO name> (e.g., drugs, routine physical exam, eyeglasses, dental, etc.) benefits, call our Customer Service Department at <plan/M+CO phone number>."

- Cost contractors must describe required low-option plans as required by regulations.

- A statement must be made indicating that (Health Plan/M+CO Name)'s benefit package, premiums, co-pays and service area are all subject to change annually at the health plan's/M+CO's contract renewal time with the Medicare Program (usually January 1). Also, a statement must be made that the (Health Plan/M+CO's Name) contract with HCFA is renewed annually, and that the availability of coverage beyond the end of the current contract year is not guaranteed.

Section 3 – "MUST USE/CAN'T USE/CAN USE" CHART

The following chart provides guidance on language that M+COs must use, can't use, and can use in advertising and member retention materials. The following items: Lock-in, Eligibility, and Contract with the Government are required items in advertising and marketing materials.

Subject	**Must Use**	Can't Use	**Can Use**	**Reason**
Lock-in	• Enrolled members "must use (name of health plan/M+CO) (contracting, affiliated, or name of health plan/M+CO participating) providers for routine care" • "Health plan/M+CO available to all Medicare beneficiaries" MEDIA: All except outdoor advertising. *Outdoor advertising has the option of excluding this topic. ***** See definition of outdoor advertising in Section 1 of this Chapter. This information may be either in the text of the piece or in a disclosure paragraph at the end/bottom of the piece.	• "Participating providers" unless you use health plan/M+CO name	• Enrolled members "must use (name of health plan/M+CO) (contracting, affiliated, or name of health plan/M+CO participating) providers for routine care"	HCFA requires lock-in for all media to inform beneficiaries of managed care requirement. Because of the length of the messages and the nature of outdoor advertising, this topic does not apply to outdoor advertising.

Subject	Must Use	Can't Use	Can Use	Reason
Descriptions of the M+CO's Quality [11]		• Superlatives (e.g. highest, best)12 • Unsubstantiated comparisons with other M+COs • Direct negative statements about other M+COs including individual statements from members or former members	• Qualified superlatives (e.g. among the best, some of the highest) • Superlatives (e.g. ranked number 1), if they can be substantiated (Source must be identified in the advertising piece.) See page 14-15 for more information. • "Health plan/M+CO delivers (adjective) quality of care." • Descriptions of health plan/M+CO's initiatives related to quality. • Can use satisfaction survey results. E.g. "The <name of specific study> indicated we rated highest in member satisfaction." (Must disclose year and source.) See page 14 for more information. • M+COs may use CAHPS survey data regarding their own organization but may not use it to make specific comparisons to other M+COs. MEDIA: All	

[11] [Note to health plan/M+CO: HCFA has the discretion to disapprove language based on site visit reviews identifying substantial deficiencies in health plan/M+CO operations.]

[12] [Note to health plan/M+CO: A member of the health plan/M+CO may use a superlative in relating their personal experience with the health plan/M+CO so long as the testimonial is preceded with the phrase "in my opinion" (e.g., "I have been with the health plan/M+CO for 10 years and *in my opinion* they have given me the best care possible.") If the member does not preface the superlative statement with the "in my opinion" phrase, the member must substantiate the statement with an acceptable qualifying information source.]

Subject	Must Use	Can't Use	Can Use	Reason
Premiums/Costs	• If a health plan/M+CO premium is mentioned, it must be accompanied by a statement that beneficiaries must continue to pay Part B premium or Medicare premium. • If an annual dollar amount/limit is mentioned, quarterly or monthly limits must also be mentioned as well as any ability to carry over any remaining benefit from quarter to quarter. MEDIA: Print • TV-Part B caveat must be flashed in TV safe range or mentioned in narration.	• "No premium" • "No premiums or deductibles" • "Free"	The following may be used. • "No health plan/M+CO premium." • "Health plan/M+CO premium equals _____" • "$0 health plan/M+CO premium" • "At no extra cost to you" but only if referring to a specific benefit • "No health plan/M+CO premiums or deductibles" • "No premiums or deductibles (you must continue to pay the Medicare Part B premium)" • "No premium beyond your monthly Medicare payment" • "No premiums other than what you currently pay for Medicare" MEDIA: All except outdoor advertising, which has the option of excluding this topic.	Materials must disclose that beneficiaries must continue to pay the Part B premium and continue their Medicare Part B coverage while enrolled in the HMO. Because of the length of the messages and the nature of outdoor advertising, this topic does not apply to outdoor advertising.
Testimonials	• Content must comply with HCFA marketing guidelines, including statements by members.	• Cannot have non-members say he/she belongs. (Can use actors, but they cannot say they belong to the health plan/M+CO.) • Speaker must identify specific health plan/M+CO membership • Ads must include a verbal statement by member indicating that s/he is a member of a specific plan or a "banner" at the bottom of the screen indicating the same or a voice over identifying the member as an enrollee of the specific plan. MEDIA: All		

Subject	Must Use	Can't Use	Can Use	Reason
Contract with the Government	• Must include one of the phrases from the can use column MEDIA: All except outdoor. Outdoor advertising, which has the option of excluding this topic. This information may be either in the text of the piece or in a disclosure paragraph at the end/bottom of the piece.	• "Recommended or endorsed by Medicare" • Cannot imply that health plan/M+CO has a unique or custom arrangement with the government, e.g.: -- "Special contract with Medicare" --"Special health plan/M+CO for Medicare beneficiaries"	• "An HMO with a Medicare contract" • "An M+CO with a Medicare contract" • "A Federally Qualified HMO with a Medicare contract" • "A Federally Qualified Medicare contracting HMO" • "Medicare approved HMO" • "A Coordinated Care Plan with an Medicare+Choice contract" • "M+C PSO" MEDIA: All	Because of the length of the messages and the nature of outdoor advertising, this topic does not apply to outdoor advertising.
Physicians and Other Health Care Providers	• If the number of physicians and other health care providers is used, it must include only those available to Medicare beneficiaries MEDIA: TV, radio, outdoor • If the number of physicians and other health care providers is used, it must include only providers available to Medicare beneficiaries. If a total number is used it must separately delineate the number of primary care providers and specialists included. MEDIA: Print and direct mail • If the M+CO uses the name and/or picture of providers and/or facilities to market itself, the provider information may only be used within the context of informing beneficiaries of providers that are associated with the M+CO? s delivery system. MEDIA: Print and direct mail	• Implication that providers are available exclusively through the particular HMO unless such a statement is true • "Participating providers" unless you use health plan/M+CO name • The M+CO may not identify itself by the name of a participating provider or provider group.	• "(Health plan/M+CO's name) participating providers" • "Network" providers • "Contracting" providers • "Affiliated" providers • Number of providers should be same total number of Medicare providers MEDIA: All	Do not use the word "participating" when referring to health plan/M+CO providers (unless you use health plan/M+CO name), since it could be confused with a participation agreement with Medicare. Health plan/M+COs should either use "contracting" or "health plan/M+CO name" when referring to health plan/M+CO providers. It must be clear to the beneficiary with whom the M+C contract with HCFA is held.

Subject	Must Use	Can't Use	Can Use	Reason
Eligibility	• Must indicate that all Medicare beneficiaries may apply - 1876 cost-contracting health plans. • Must indicate that all Medicare beneficiaries with Parts A and B of Medicare may apply - M+C plans. • Must indicate that beneficiaries must be entitled to Part A and enrolled in B This information may be either in the text of the piece or in a disclosure paragraph at the end/bottom of the piece.	• "No health screening" unless specific mention is made of ESRD • "Seniors" unless term appears with "and all other Medicare eligibles" • "Health plan/M+CO designed especially for seniors" • "Senior health plan/M+CO" unless part of health plan/M+CO name • "Individuals age 65 and over"	• "Anyone with Medicare may apply" • "Medicare entitled by age or disability" • "Individuals eligible for Medicare by age or disability" • "Individuals on or entitled to Medicare by age or disability" • "Medicare beneficiaries" • "Medicare enrollees" • "People with or on Medicare" • "No physicals required" • "No health screening" if a caveat is included for ESRD MEDIA: ALL	Since all Medicare beneficiaries may enroll in Medicare-contracting HMOs, you may not refer to your health plan/M+CO as a "senior health plan/M+CO" (unless you refer to it as part of the health plan/M+CO name). The term "senior health plan/M+CO" implies that disabled beneficiaries may not enroll. Medicare Part A is not a requirement for enrollment in Medicare-cost contracting HMOs. M+COs may only enroll individuals with both Parts A and B of Medicare, with the exception of " grandfathered" members.
Claims Forms/ Paperwork		• "No paperwork" • "No claims or paperwork/complicated paperwork" • "No claims forms"	• "Virtually no paperwork" • "No paperwork when using health plan/M+CO providers" • "Hardly any paperwork" MEDIA: All	Members may be required to submit bills or claims documentation when using out-of-plan providers.

Subject	Must Use	Can't Use	Can Use	Reason
Benefits				
a. Comparison	• If premiums and benefits vary by geographic area, must clearly state this or must clearly state geographic area in which differing premiums and benefits are applicable. • If only benefits vary, clearly state geographic area in which benefits are applicable. MEDIA: All	• Minimal co-pays may vary by county • Minimal co-pays may apply	• "Premiums and benefits may vary by county" or "These benefits apply to the following counties"* • "Except for _____ county"* MEDIA: All • M+COs may compare benefits to Medigap plans as long as information is provided accurately and in detail.	Premiums, benefits, and/or copayment amounts may vary by county within a given service area. This must be clearly conveyed in all marketing materials.
b. Limitations		• "At no extra cost to you" or "free" if co-pays apply	• State exact dollar amount limit on any benefit • "Limitations and restrictions may apply" • "Minimal copayments will apply" • "Minimal copayments vary by county"* • State which benefits are subject to limitations MEDIA: All	If benefits are specified within the piece, any applicable copayment should be stated or you may include the general statement as shown.
c. Prescription Drugs	If prescription drugs are mentioned and have limitations, must say: • limited outpatient drug coverage; • drug coverage benefits subject to limitations; or • up to xxx annual/quarterly/monthly limit or xxx limit per year/quarter/month and other limits and restrictions may apply. • copayment amounts and indicate for a xx number of days supply If benefits are restricted to a formulary, this must be clearly stated. In addition, must state • that formulary contents are subject to change within a contract year without advance notice • health plan/M+CO should be contacted for additional details. MEDIA: All	• "We cover prescription drugs" unless accompanied by reference to limitation • "Prescription drug coverage" unless accompanied by reference to limitation	• Fully disclose dollar amount of copayments and annual/quarterly/monthly limit • If limited, you must say so • Limited outpatient drug coverage with xx copayments for xx number of days supply and xxx annual/quarterly/monthly limit • "Prescriptions must be filled at contracting or health plan/M+CO affiliated pharmacies." MEDIA: All	Prescription drugs are an important benefit that must be adequately described. Any dollar limits must be clearly conveyed.
d. Multi-year Benefits	Whenever multi-year benefits are discussed, M+COs are required to make appropriate disclosure that the benefit may not be available in subsequent years. MEDIA: All, where multi-year benefit(s) are mentioned		• "[benefit] may not be available in subsequent years" OR • "[name of M+CO] contracts with Medicare each year, this benefit may not may not be available next year" MEDIA: All, where multi-year benefit(s) are mentioned	OPL 99.101 dated September 23, 1999. Potential applicants and members must be informed in marketing materials that multi-year benefits in current year benefit packages are not guaranteed in future contract years.

***NOTE: Flexible benefits are not permitted under the M+C program. Therefore, premiums, co-pays and benefits may not vary by county for the same M+C plan.**

Subject	Must Use	Can't Use	Can Use	Reason
Definitions -- Emergency and Urgently Needed Care		• "Life threatening" • "True emergency"	• Emergency -- definition as stated in current HCFA policy. • Urgent -- definition as stated in current HCFA policy. MEDIA: All	Emergency and urgent care criteria should be explained per Medicare guidelines rather than in the commercial context.
Drawings/prizes		• "Eligible for free drawing and prizes" MEDIA: Direct mail, flyers, print advertising	• "Eligible for a free drawing and prizes with no obligation" • "Free drawing without obligation" MEDIA: Direct mail, flyers, print advertising.	It is a prohibited marketing practice to use free gifts and prizes as an inducement to enroll. Any gratuity must be made available to all participants regardless of enrollment. The value of any gift must be less than the nominal amount of $10.
Sales presentations	• "A sales representative will be present with information and applications." MEDIA: Flyers and invitations to sales presentations • "A sales representative may call." MEDIA: Response card where the beneficiary's phone number is requested • "A telecommunications device for the deaf (TDD) is available to get additional information or set up a meeting with a sales representative." MEDIA: All • "For accommodation of persons with special needs at sales meetings, call (Health Plan Phone Number)." MEDIA: Flyers and invitations to sales meetings	• "A health plan representative will be available to answer questions."		This phrase must be used whenever beneficiaries are invited to attend a group session with the intent of enrolling those individuals attending. This phrase must be included on any response card in which the beneficiary is asked to provide a telephone number. All Health plans must indicate in all advertising that a telecommunication device for the deaf (TDD/TTY) is available to get additional information or to set up a meeting with a sales representative.

Chapter 4 --
Guidelines for Beneficiary Notification Materials

The definition of marketing materials includes all notification forms and letters used to enroll, disenroll and communicate with the member on many different membership operational policies and procedures. These materials are also described as beneficiary notification materials and subject to specific HCFA requirements. Section 1 of this chapter provides general guidance with respect to beneficiary notification materials, including the review process. All beneficiary notification materials are subject to Final Verification Review, a process that is described in Section 2 of this chapter. Section 3 provides specific guidance with respect to provider directories. Section 4 provides specific guidance about the use of drug formularies.

Section 1 -- General Guidance for Beneficiary Notification Materials

Use of Model Beneficiary Notification Materials

Beneficiary notification materials are those materials used by health plans/M+COs to convey benefit or plan operational information to potential or enrolled beneficiary health plan members. Model beneficiary notification material usage generally falls into one of two categories:

1) Those materials that are used for routine communications between the health plan/M+CO and the beneficiary and contain content that does not change appreciably from year to year (e.g., enrollment letters and disenrollment confirmation).[13] These materials require individual addressee information, but no changes to the body of the model document and can be used **without HCFA review/approval**. HCFA will check samples of these materials on monitoring visits to ensure compliance with the "no modification" condition associated with this policy.

2) Those materials that contain information that announce changes (usually on an annual basis) in the services or contractual arrangements between the beneficiary and the health plan/M+CO (e.g., the Evidence of Coverage, Member Handbook, Summary of Benefits, and Annual Notice of Change Letter.)[14] These materials contain information that must be inserted within the standard model text in the body of the document (e.g., premiums, service access information, and benefits/utilization) and require **partial review/approval by HCFA**. HCFA will review only the information that must be inserted into the document. This policy is designed to expedite review of the material. As with the items described in category 1 above, HCFA will review samples of these materials on monitoring visits to ensure compliance.

Use of model beneficiary notification materials by health plans is voluntary. Any changes to model notification materials requires either partial or full review/approval by HCFA. Use of non-model notification materials requires full review/approval by HCFA.

[13] Model materials in this category are provided in OPL 99.100, "Medicare+Choice Enrollment and Disenrollment Policies," August 9, 1999, available on HCFA's web site at: www.hcfa.gov/medicare/index.htm.

[14] Model materials in this category and the standardized Summary of Benefits are also available at HCFA's web site at: www.hcfa.gov/medicare/mgdmktg.htm.

Use of Standardized Beneficiary Notification Materials

HCFA has initiated a program to develop and implement standardized beneficiary notification marketing materials for health plan participants in Medicare managed care. As part of the first phase of this program, all Medicare+Choice Organizations were required to use a standardized Summary of Benefits (SB) beginning in contract year 2000. (Specific information, including instructions and frequently asked questions and answers are available on the HCFA web site at: www.hcfa.gov/medicare/mgdmktg.htm.) The same two categories of notification materials and HCFA review/health plan utilization of these materials described in the above model notification material directive also apply for standardized notification materials. **Use of standardized notification materials by health plans/M+COs is <u>mandatory</u>.**

Employer Group Health Plans (EGHPs) were granted an exemption from this requirement to use the standardized Summary of Benefits while HCFA conducted a review to determine whether EGHPs should receive a permanent exemption. After discussions with various interested parties, including employer groups, consulting firms, beneficiary advocacy groups, and employer unions, HCFA has decided to exempt EGHPs from the requirement to use HCFA's standardized Summary of Benefits.

HCFA is also working with interested parties to develop a standardized EOC and enrollment application for contract year 2002. HCFA will also be standardizing other enrollment and appeals-related notices.

Section 2 -- Final Verification Review Process[15]

Beneficiary notification materials described in category 2 above are subject to HCFA's final verification review process, in which the materials are reviewed at the final proof stage. This final proof is usually the printed document or electronic file that is sent to the health care organization by the printer prior to printing. When approval is given by the organization based on review of the final proof, the electronic file is transmitted to the printer for execution of the print job. Under special circumstances when final proof copy is not available, blue-line or camera ready copy may be substituted for final proof copy in the final verification review procedure.

In cases where the health plan makes its own reproductions of a document rather than using a printer, a final copy of the document that will be used as the master for the reproductions will be required. Health plans/M+COs may request RO permission to submit marketing materials electronically for review. However, electronic transmission of documents and approval/rejection notifications by the RO is not required.

When the final text or script version of the beneficiary notification material is satisfactory and the final proof needs to be submitted to HCFA For approval, the material is designated by HCFA as "acceptable." Approval stamps ***should not*** be affixed to documents in this stage of the review process. The RO should indicate that material is not yet the final-proof version, by appending the suffix "txt" to the file. Once the final proof is approved by HCFA and the marketing material can be published and distributed by the M+CO, the material is considered, "approved" and approval stamps (or other methods of indicating approval) should be fixed to document at this

[15] Final Verification Review is outlined in OPL 99.106, AFinal Verification Review of Medicare Managed Care Marketing Materials,@ published on November 10, 1999 and available on the HCFA website at: www.hcfa.gov/medicare/index.htm.

stage in the process. The RO should indicate that the material is a final proof version by appending the suffix "fv" to the file.

HCFA marketing reviewers will stress detection of errors during the initial text review(s) of the material. This effort will, to the extent possible, avoid costly revisions at the "camera ready" or "final proof" review stage. The final verification review is conducted to confirm that the final proof version contains no changes from the initial text version that was approved by HCFA.

Section 3 -- Specific Guidance for Provider Directories

Regulations at 42 CFR 422.111(b) require that M+COs disclose the following information to each enrollee electing an M+C plan offered by the M+CO:

1) the number, mix, and distribution, including addresses of providers from whom enrollees may obtain services, as well as any out-of-network coverage or point-of-service option;

2) information regarding out-of-area coverage and emergency coverage, including the process and procedures for obtaining emergency services and the location where emergency care can be obtained as well as other locations where contracting physicians and hospitals provide emergency services and post-stabilization care included in the M+C plan;

3) prior authorization rules and other review requirements that must be met in order to ensure payment for the services; and

4) instructions to enrollees that, in cases where noncontracting providers submit a bill directly to the enrollee, the enrollee should not pay the bill, but submit it to the M+CO for processing and determination of enrollee liability, if any.

Section 422.111(a) requires that this information be disclosed in clear, accurate, and standardized form at the time of enrollment and at least annually thereafter.[17] M+COs generally include this information in their provider directory and distribute the directory to new members upon enrollment and existing members on an annual basis.[18] In addition to the information provided above, provider directories must also contain the following:

1) Names, complete addresses, and phone numbers of the primary care physicians;

2) Names and addresses (city or town) of specialists, skilled nursing facilities, hospitals, outpatient mental health providers, and pharmacies, where outpatient prescription drugs are offered by the M+C plan;

[17] In accordance with the National Marketing Guidelines, this information should be provided in at least 12-point font size.

[18] M+COs may choose to disseminate an errata sheet or addendum during the year to update members with respect to changes in providers' addresses and phone numbers. However, in accordance with 42 CFR 422.111(c), M+COs must disclose any changes to the provider information upon request and, under 422.111(e), must notify members of changes to the provider network within 15 working days of receipt of issuance of a notice of provider termination. M+COs should consult the M+C regulations for further information.

3) General information regarding lock-in, including the role of the primary care physician (PCP) as well as the process for selecting a new PCP and any specific requirements for referrals to specialists and ancillary providers;

4) A description of the plan's service area, including a list of cities and towns;

5) Telephone numbers for customer service or appropriate contact information (including the hours of service) for members who have questions or require assistance in selecting a PCP;[19] and

6) A general disclaimer that indicates that the directory is current as of a particular date and that a provider's listing in the directory does not guarantee that the provider is still in the network or accepting new members.

M+COs that use subnetworks of providers must clearly delineate these sub-networks (preferably by listing the providers as a separate subnetwork) and describe any restrictions imposed on members that use these subnetworks. This is particularly important since beneficiaries could choose their primary care physician without realizing that this choice restricts them to a specified group of specialists, ancillary providers, and hospitals. M+COs must also clearly describe the process for obtaining services in these networks and sub-networks, including any referral requirements, as well as any out-of-network coverage or point-of-service option.

M+COs may find it more economical to print a separate directory for each sub-network and disseminate this information to members in a particular subnetwork. This practice is permissible, provided that the directory clearly states that a directory that lists providers for other networks is available and provides this information to members upon request.

Section 4 -- Specific Guidance about Drug Formularies

In providing a prescription drug benefit, a health plan/M+CO may rely on a formulary. A formulary is a list of prescription drugs, grouped by therapeutic drug class. There are three categories of formularies: open, incentivized, and closed. Open formularies list all drugs and drug products and rank products that the health plan/M+CO prefers. Incentivized formularies are similar to open formularies, but also use incentives and interventions to encourage use of preferred drugs. An increasingly common form of incentivized formularies is known as the three-tier copay benefit design. Under this model, consumers pay the lowest price for generic drugs, somewhat more for brand-name drugs on a preferred list, and the highest price for brand-name drugs not on the list. Closed formularies use limited lists of drugs; enrollees pay penalties (sometimes the entire cost) to use drugs not on the list.

Many health plans/M+COs make periodic changes to formularies or the items on preferred lists, often convening meetings of their pharmacy and therapeutics committees several times a year to add and remove items from the formulary or preferred list. When they enroll in a Medicare+Choice plan, beneficiaries may not be aware that changes to formularies or preferred lists are likely to occur during the contract year.
Every health plan/Medicare+Choice organization that covers outpatient prescription drug benefits (those not covered under the original Medicare fee-for-service program) must provide

[19] In accordance with the National Marketing Guidelines, the applicable TDD/TTY number must also be provided, including the hours of operation.

notice in its Evidence of Coverage (EOC) whether it uses a formulary or preferred list. If it uses formularies or preferred lists, the notice shall include:

- an explanation of what a formulary is;
- a statement that the formulary (or drugs on the preferred list) may change during the contract year;
- an estimate of how often the health plan/M+CO reviews the contents of the formulary and makes changes based upon that review;
- a description of any process by which a prescribing provider may obtain authorization for a nonformulary or non-preferred list drug to be furnished under the same terms and conditions as drugs on the formulary or preferred list; and
- a statement that members may use health plan/M+CO grievance and complaint processes if they have complaints about the formulary or its administration.

In addition, health plans/M+COs that use formularies or preferred lists must disclose whether specific drugs are on the health plan/M+COs' formularies or preferred lists when enrollees or potential enrollees make telephone or other inquiries.

With respect to pre-enrollment marketing materials that describe plan benefits, health plans/M+COs must disclose whether a formulary or preferred list is used and that the formulary or list may change during the contract year and provide a contact number that the beneficiary can call for more information. This policy will be effective beginning in contract year 2001 and will be incorporated into the Model EOC for 2001.

Section 5 -- Guidance to Medicare+Choice (M+C) Organizations About Outreach to its Dual Eligible Membership

Medicare+Choice (M+C) Organizations have recently shown an interest in conducting outreach to their current M+C enrollees and screening for whether or not they are potentially eligible for state financial assistance through state Medicaid programs. HCFA recognizes the potential financial benefits of such outreach to the M+C enrollees (as illustrated in the following dual eligibility chart) and to the M+C Organizations[20] and encourages organizations to provide this kind of assistance to its members. HCFA also recognizes the need to maintain each enrollee's right to financial privacy and protection from unwelcome solicitation and undue pressure to apply for these additional benefits.

This Section provides guidelines that M+C Organizations[21] must follow in designing and carrying out state financial assistance outreach, which HCFA considers to be marketing according to the definition in 42 CFR 422.80(b)(3), in that such activity explains benefits and rules that apply to dual eligible enrollees. Such activity also can be seen to promote the M+C organization engaging in the outreach, which in such a case would fall under section 422.80(b)(3).

NOTE: Only the appropriate state/county agency can make a final determination on eligibility for state financial benefits. In no way can the M+C Organization represent itself as being able to adopt that role.

Dual Eligibility

There are several categories of dual eligibles, each having specific income requirements and receiving different levels of financial assistance. The categories are outlined in the following chart.

Eligibility Category	Income / Resource Level	Medicaid Assistance
QMB Qualified Medicare Beneficiaries without other Medicaid	Income at or below 100% federal poverty level (FPL), resources at or below twice limit under SSI program, not otherwise eligible for Medicaid	Payment of Medicare premiums, deductibles, and coinsurance
QMB+ Qualified Medicare Beneficiaries with Full Medicaid	Income at or below 100% FPL, resources at or below twice limit under SSI program	Payment of Medicare premiums, deductibles, and coinsurance plus full Medicaid benefits
SLMB	Income greater than 100% but	Full payment of Medicare Part

[20] The monthly capitation rate for an M+C enrollee that HCFA pays to the M+C Organization is higher for an enrollee who is a Medicaid recipient because this beneficiary tends to have higher medical costs than a Medicare beneficiary who is not a Medicaid recipient. HCFA does not pay the Medicaid adjustment factor for Qualified Individuals-2 or Qualified Individuals-1.

[21] The Organization is ultimately responsible for outreach even if the task is delegated to another entity. See section on Delegation on page 4.

Eligibility Category	Income / Resource Level	Medicaid Assistance
Specified Low-Income Medicare Beneficiaries without other Medicaid	less than 120% FPL, resources at or below twice limit under SSI program, not otherwise eligible for Medicaid	B premiums
SLMB+ Specified Low-Income Medicare Beneficiaries with Full Medicaid	Income greater than 100% but less than 120% FPL, resources at or below twice limit under SSI program	Full payment of Medicare Part B premiums plus full Medicaid benefits (which may, at State option, include Medicare deductibles and coinsurance)
QDWI Qualified Disabled and Working Individuals	Eligible to purchase Medicare Part A, income less than or equal to 200% FPL, resources not exceeding twice limit under SSI program	Full payment of Medicare Part A Premiums
QI-1s Qualifying Individuals-1	Income greater than or equal to 120% but less than 135% FPL, resources at or below twice limit under SSI program	Full payment of Medicare Part B Premiums
QI-2s Qualifying Individuals-2	Income greater than or equal to 135% but less than 175% FPL, resources at or below twice limit under SSI program	Partial payment of Medicare Part B premiums

OUTREACH PROGRAM GUIDANCE

An M+C Organization conducting a dual eligibility outreach program to its membership must provide members with information on *all* levels of dual eligibility. It cannot restrict information sharing or assistance from members who may qualify as QI-1s or QI-2s, members who may not provide additional revenue to the M+C Organization through increased capitation payments.

Disclosure to HCFA

An M+C Organization that would like to conduct such outreach must first submit a written proposal to its HCFA Central Office Plan Manager and a copy to the Regional Office Plan Manager. This proposal must include:

- A flow chart or written description of the entire outreach process including all the steps involved and parties responsible for each step;
- Draft model beneficiaries letters (if applicable), the number of beneficiaries targeted, their general locations (if effort targets more than one service area) and the date(s) on which the M+C Organization will mail the letters;
- Telephone scripts to be used by parties conducting telephone outreach (if applicable);
- Description of contractual arrangements with all external entities involved in the outreach effort;
- Written substantiation of member privacy protections.

HCFA's Central and Regional Office Plan Managers will review the proposal and draft documents and will respond in writing to the M+C Organization within the 45-day time frames established for other marketing material. **The M+C Organization must receive HCFA approval for all outreach documentation before using them in this outreach effort.**

Contact Initiation

An M+C Organization may initiate outreach to its members through written communication and/or via the telephone. The M+C Organization may **not** initiate outreach through door-to-door solicitation.

Written Communication

An M+C Organization may send outreach letters to targeted M+C enrollees. These letters must include the following information:

- Financial benefits and income/asset and other eligibility requirements;
- Telephone numbers for the appropriate State Medicaid Agency and/or the State Health Insurance Assistance Program (SHIP);
- A statement that all enrollee actions are voluntary and that the enrollee need not take further action if he or she chooses not to.
- Assurance that the M+C organization will not share the information that the enrollee discloses

Attachment A is a model outreach letter developed by HCFA's Center for Medicaid and State Operations (CMSO). HCFA encourages M+C Organizations to use this letter as a template in developing outreach letters before submitting them to HCFA for review.

Telephone Communication

In all telephone communications, the M+C Organization must:

- Clearly state that the beneficiary may *voluntarily* offer financial information necessary to receive a preliminary eligibility determination but is not required to do so;
- Inform the member that the Organization cannot make a final eligibility determination; it can only provide an initial screening. It must explain that the member will have to submit a completed application to the appropriate state/county agency for a final determination and that the agency will notify the member of their eligibility status;
- Discuss all levels of eligibility requirements and benefits regardless of whether or not the member's potential eligibility qualifies the M+C Organization for the increase in capitation payment from HCFA.

Face-to-Face Contact

The M+C Organization cannot conduct “door-to-door” solicitation to initiate the outreach program. However, if the enrollee verbally or in writing requests a home visit, a representative from the M+C Organization may provide screening assistance in the home.

Data Collection

HCFA recognizes that in order to provide this screening service to its members, the M+C Organization will have to gather some financial information from them. However, the organization cannot maintain this information after the screening process is complete and cannot, under any circumstances, use this information for any purpose other than the screening.

Application Completion

If the M+C member requests help, the M+C Organization may assist the member with completing and submitting the required paperwork to the State/County for final eligibility determination. This may also take place in the member's home, but only if he or she requests the visit from the Organization.

Delegation

An M+C Organization may wish to contract with or delegate another entity to perform part or all of the dual eligibility outreach functions. Under this scenario, HCFA will continue to hold the M+C Organization responsible for ensuring that the delegated or contracted organization meets all the guidelines in this OPL and that the M+C Organization is protecting each enrollee from privacy violations. HCFA reserves the right to review such delegation contracts to ensure these protections are in place.

Dual Eligibility Reporting to HCFA

M+C Organizations normally responsible for submitting Medicaid eligibility data to HCFA should not identify QI-1s or QI-2s because HCFA does not consider these two categories of dual eligibles as eligible for the Medicaid adjustment factor. The Medicaid adjustment will be factored into the payment of all other categories of dual eligibles.

Notification to Partners

If HCFA approves the outreach initiative, the Regional Office will furnish HCFA's partners, specifically (SHIPs) and the appropriate State Medicaid Agency with copies of all outreach letters, the number and locations of letters being sent, and the dates on which the Organization is mailing them.

Direct Mail Letter

August 25, 2000

Mr. Frank Smith
123 Maple Lane
Anywhere, USA 12345

Dear Mr. Smith,

Did you know you may be able to save up to $546 a year on Medicare expenses?

There are programs that save millions of people $34 to $546 in their Social Security checks, each year! If you answer "yes" to ALL three of these questions, then you may qualify for Savings for Medicare Beneficiaries.

- Do you have Medicare Part A, also known as hospital insurance? If you are eligible for Medicare Part A, but do not have it because you cannot afford it, you may still qualify because there is a program that will pay the Medicare Part A premium.
- Are you an individual with a monthly income of less than $1,238 or a couple with a monthly income of less than $1,661?
- Are you an individual with savings of $4,000 or less or a couple with savings of $6,000 or less? Savings include things like money in a checking account or savings account, stocks, or bonds. When you are figuring out your savings, do not include your home, a car, burial plots, up to $1,500 for burial expenses, furniture, or $1,500 worth of life insurance.

Enclosed is a brochure that gives you more information about the programs that can help you save on your medical expenses, information on who qualifies, and how to apply for the programs.

I hope you will call me between 9 a.m. and 5 p.m. Monday through Friday at (your phone number here) for more information or for help joining one of these programs. All information that you share will only be used to determine if you may be able to get help with your medical expenses. I will not share the information with anyone else. I encourage you to call to see if you can receive help with your medical expenses, but the choice is yours. You are not required to call. If you like, you can also receive information about the programs by calling a representative of the State Health Insurance Assistance Program at **XXX** or a State representative at **XXXX**. Deaf or hearing-impaired people who use a TTY/TDD can call Medicare's national help line at 1-800-486-2048. When you call, ask about programs that can help with Medicare expenses.

Chapter 5 -- Guidelines for Promotional Activities

This chapter reviews the use of promotional activities relating to the enrollment and retention of members. Section 1 of this chapter provides general guidance about promotional activities, while Section 2 provides specific guidance for provider promotional activities. Section 3 answers some frequently asked questions regarding all aspects of promotional activities. Section 4 provides specific guidance about Value-Added Items and Services, while Section 5 describes HCFA's policy with respect to the use of independent insurance agents for marketing purposes. Definition and policy changes in this chapter are a result of compliance with directives from the Office of Inspector General regarding monitoring of Medicare managed care operations under several statutes which prohibit unlawful influence/inducement of Medicare beneficiaries.

Section 1 -- General Guidance About Promotional Activities

Promotional activities (including provider promotional activities) must conform to the requirements of Sections 1128A(a)(5) and 1128B(b) of the Social Security Act. Section 1128A(a)(5) of the Act provides for a civil monetary penalty against a person or entity that offers or transfers remuneration to a Medicare or Medicaid eligible individual that the person or entity knows or should know is likely to influence such eligible individual to receive or order services from a particular provider (including an HMO). Section 1128B(b) of the Act, the Medicare and Medicaid anti-kickback statute, prohibits the offering or giving of remuneration to induce the referral of a Medicare or Medicaid beneficiary, or to induce a person to purchase, or arrange for, or recommend the purchase or ordering of an item or service paid in whole or in part by the Medicare or Medicaid programs. Additional prohibitions on the offering of monetary rebates or inducements of any sort to enrollees are contained in section 1854(d) of the Act.

Nominal Gifts

Many health plans/M+COs offer gifts to potential enrollees if they attend a marketing presentation. Section 2211 of the Medicare Managed Care Manual permits this practice as long as such gifts are of nominal value and are provided whether or not the individual enrolls in the health plan/M+CO. Nominal value is defined as an item worth $10 or less, based upon the retail purchase price of the item. Local Medicare fee-for-service Fiscal Intermediary and/or Carrier charge listings can be used to determine the value of medical services, examinations, laboratory tests, etc., associated with nominal value determinations in marketing scenarios. Cash gifts are prohibited including charitable contributions made on behalf of people attending a marketing presentation and including gift certificates that can be readily converted to cash, regardless of dollar amount. This definition supersedes that found at section 2211.C in the Medicare Managed Care Manual. The dollar amount associated with the definition will be periodically reassessed by HCFA.

Referral Programs

The following general guidelines apply to referral programs under which health plans/M+COs solicit leads from members for new enrollees. These include gifts that would be used to thank members for devoting time to encouraging enrollment. Gifts for referrals must be available to all members and cannot be conditioned on actual enrollment.

- Health plans/M+COs may not use cash promotions as part of a referral program.

- Health plans/M+COs may offer thank-you gifts of less than $10 nominal value (e.g., thank you note, calendar, pen, key chain) when an enrollee responds to a health plan/M+CO solicitation for referrals. These thank you-gifts are limited to one gift per member, per year.

- A letter sent from the health plan/M+CO to members soliciting leads cannot announce that a gift will be offered for a referral.

Health Fairs and Health Promotional Events

Many health plans/M+COs are interested in offering health fairs or social events that promote health awareness and a sense of belonging among seniors. Health plans/M+COs may participate in such events as either the sole sponsor of the event or as a member of a multiple-sponsor event. Application of the following HCFA policies to the condition of sponsorship is indicated by (Sole-Sponsor) for sole sponsor events, (Multiple-Sponsor) for multiple-sponsor events, and (Both) where the policy applies to both single and multiple sponsor events. If an audience is comprised of the general public as well as Medicare beneficiaries, the following policies apply to the entire audience:

- Such events should be social and should not include a sales presentation. (Both) Response by a health plan/M+CO representative to questions will not be considered a sales presentation if no enrollment form is accepted at the event. (Both)

- Advertisements for the event can be distributed to both members and non-members. (Both)

- The value of any give-away or free items (e.g., food, entertainment, speaker) cannot exceed $10 per attending person. For planning purposes, event budgets can be based on projected attendance. The cost of overhead for the event (e.g., room rental) is not included in the $10 limit. (Both)

- Pre-enrollment advertising materials (including enrollment forms) can be made available as long as enrollments are not accepted at the event. (Both)

- If offered, door prizes/raffles cannot exceed the $10 limit. (Sole-Sponsor) However, door prizes/raffles can exceed the $10 limit if a health plan/M+CO contributes to a pool of

cash for prizes or contributes to a pool of prizes such that the prize(s) is not individually identified with the health plan/M+CO, but is identified with a list of contributors. A jointly-sponsored event may consist of the health plan/M+CO and one or more sponsor participants who are not contracting providers with the health plan/M+CO. A health plan/M+CO may also contribute cash toward prize money to a foundation or another entity sponsoring the event. For example: A radio station, along with many sponsors, puts together a seniors fair. Anyone who attends may register for the door prize: a get-away weekend. The health plan/M+CO may participate in the fair, contribute to the door prize, and permit attendees to register for the prize at its booth (as well as other sponsor booths). However, the health plan/M+CO cannot claim to be the sole donor of the prize. It must be clear that the prize is attached to the seniors fair. No sales presentation may be made at the event. (Multiple-Sponsor)

Employer Group Health Fairs

Enrollment restrictions (i.e., no sales presentations can be made or enrollment applications accepted at the meeting) do not apply to health fairs or other promotional events sponsored by an employer group or labor organization so long as the following requirements are met:

1. The meeting must be held solely for retirees or those soon to retire (and their spouses/interested decision makers) from the employer/labor organization. No "general public" persons may be solicited or invited to attend the meeting.

2. The meeting may not be announced via "public media" vehicles. Potential employer group/labor organization retirees must be notified of the meeting by individual notification or by company/labor organization sponsored media such as a newsletter or similar targeted mailing/vehicle.

HCFA Sponsored Health Information Fairs

The Health Care Financing Administration is required to conduct a nationally coordinated education and information campaign to inform Medicare+Choice eligible individuals about Medicare+Choice plans and the election process provided under the law for enrolling in Medicare+Choice plans. One of the coordinated education and information campaign activities is HCFA sponsorship of Medicare+Choice Health Information Fairs.[22] While most HCFA sponsored M+C Health Fairs will be conducted immediately before and during the month of November each year (the Annual Election Period), occasionally HCFA will sponsor Health Fairs as early as September and other times of the year. The following rules and procedures apply to HCFA-sponsored Health Fairs, whenever they occur.

HCFA will invite the M+C Organizations to participate in the planning of local Health Fairs. M+CO participation is optional, but it is important to get current contractors to the planning

[22]Section 1851(e)(3) of the Act and 42 CFR 422.10(b).

table. It is imperative that all HCFA Regions are consistent in applying participation guidelines at these HCFA-Sponsored Health Fairs. Below are the guidelines. **HCFA retains the right to modify these guidelines, if HCFA encounters a new situation which must be addressed.**

Medicare+Choice Organizations MAY do the following:

- Assist in the planning of local Health Fairs.
- Distribute health plan brochures and Enrollment By Mail Forms (EBMFs), while at the Health Fair.[23] They may also include in their handouts a reply card which may be given to interested beneficiaries for return to the organization via mail.
- Have a booth at the Health Fair.
- Distribute items with a total retail value of no more than $10. These items MUST be offered to everyone, (e.g. organizations can not give gifts to only those individuals who show interest).
- Have any personnel present (i.e. marketing personnel, customer service personnel) as long as they adhere to these guidelines.
- Contribute funding for any Health Fair costs (i.e. purchasing of food; drawings, raffles, or door prizes for attendees which exceed the $10 nominal value requirement) as long as the recognition of the donation is to a number of entities (not just one particular M+C Organization).

Medicare+Choice Organizations may NOT do the following:

- Give sales presentations.
- Market their non-Medicare commercial products.
- Collect enrollment applications. (Although EBMFs may be distributed, they may not be collected during HCFA-sponsored Health Fairs).
- Collect names/addresses of potential enrollees. However, as noted above, they may

[23] An EBMF may be either 1) a specifically designed enrollment application form which is attached to health plan/M+CO marketing materials; or 2) a standard health plan/M+CO enrollment application form with instructions that the form must be mailed back to the health plan M+CO. The key feature of the EBMF is that it must be completed by the beneficiary in the absence of health plan/M+CO marketing influences and returned to the health plan/M+CO by mail. (Self-addressed, postage paid, return envelopes may be provided by the health plan/M+CO.)

distribute EBMFs and reply cards.

- Compare their benefits against other health plans. However, they may use comparative information which has been created by HCFA (such as information from HCFA's website) or information/materials which have been approved by HCFA (i.e. the standardized Summary of Benefits).

- Third party created materials may not be used, unless they have been approved by HCFA in advance.

- Give individual gifts with a retail value of more than $10.00.

Section 2 -- Specific Guidance About Provider Promotional Activities

Some health plans/M+COs use their health plan/M+CO providers to help them market their Medicare product. As used in this Guide, the term "provider" means all Medicare health plan/M+CO contracting health care delivery network members; e.g. physicians, hospitals, etc. This goes beyond the Medicare regulatory definition for "provider". Section 2213 of the Medicare Managed Care Manual contains some guidance on this subject. The purpose of this section is to remind health plans/M+COs of the manual provisions and to further specify what practices in this area would meet both HCFA requirements and the needs of the health plans/M+COs.

HCFA is concerned with provider marketing for the following reasons:

- Providers are usually not fully aware of all health plan/M+CO benefits and costs; and

- A provider outside the role of providing medical services may confuse the beneficiary when the provider is acting as an agent of the health plan/M+CO vs. acting as their provider.

Providers may face conflicting incentives when tasked with both being an agent of a health plan/M+CO and knowing their patients' health status. Desires to either reduce out-of-pocket costs for their sickest patients, or to financially gain by enrolling their healthy patients may result in recommendations that do not address all of the concerns or needs of a potential health plan/M+CO enrollee.

There are some permissible provider marketing activities, however. Listed below are some requirements for these, and the reasons they are permitted:

1. Health fairs. At health fairs, provider groups and individual providers can give out health plan/M+CO brochures including Enrollment by Mail Forms (EBMFs). Because they may not be fully aware of all benefits and costs of the various health plans/M+COs, providers or their representatives cannot compare benefits among health plans/M+COs in

this setting. In addition, applications may not be taken at health fairs. (See the discussion of health fairs and health promotion events Section 1 above.)

2. Provider offices - activities and materials. In their own offices, provider groups and individual providers can give out health plan/M+CO brochures, and posters announcing health plan/M+CO affiliation (all of which must be exclusive of applications). Providers, their representatives and qualified health plan/M+CO (marketing) representatives are all prohibited from taking applications in the place where health care is delivered, such as provider offices or hospital wards. This is to prevent Medicare beneficiaries from experiencing inappropriate pressure to enroll at the time that health care is being delivered.

   When patients seek information or advice from their own physician regarding their Medicare options, physicians may engage in this discussion. Because physicians are usually not fully aware of all health plan/M+CO or original Medicare benefits and costs, they are advised to additionally refer their patient to other sources of information, such as 1-800-MEDICARE, the State Health Insurance Assistance Program, and/or specific health plan/M+CO marketing representatives. Additional information can also be found on HCFA? s website, www.medicare.gov. Physicians are permitted to printout and share information with patients from HCFA's website.

3. Health plan/M+CO and provider co-sponsorships. Providers and provider groups can co-sponsor an event, e.g., an open house or a health fair with a health plan/M+CO. Providers and provider groups and health plans/M+COs can cooperatively market and advertise by such means as TV, radio, direct mail, testimonials, posters, fliers and print ads. All materials describing the health plan/M+CO in any way must get prior approval, should have the health plan's/M+CO's name or logo on them as well as the provider's/provider group's name or logo, and must follow all of the rules in Chapter 3 -- Guidelines for Advertising Materials. All materials mentioning the health plan/M+CO are considered marketing materials and must therefore adhere to this Guide and be prior approved by HCFA.

4. Providers/provider group affiliation information. Providers/provider groups can announce a new affiliation with a health plan/M+CO to their patients. An announcement to patients of a new affiliation which names only one health plan/M+CO may occur only once. Additional contacts from providers to their patients regarding affiliation must include all the Medicare health plans/M+COs with which the provider contracts. This includes, for example, annual affiliation announcements, announcements that certain affiliations have terminated, and the display of health plan/M+CO brochures/posters. If these communications describe health plans/M+COs in any way (as opposed to just listing them), they must be prior approved by HCFA (see below).

5. Providers/provider group comparative/descriptive information. Providers/provider groups may provide printed information to their patients comparing the benefits of different health plans/M+COs with which they contract. Such materials must have the

concurrence of all health plans/M+COs involved and must be prior approved by HCFA. The health plans/M+COs may want to determine a lead health plan/M+CO to coordinate submission of these materials. HCFA continues to hold the health plans/M+COs responsible for any comparative/descriptive material developed and distributed on their behalf by their contracting medical groups and other health care providers. The providers/provider groups may not health screen when sending out such information to their patients. The reason for this is that any material sent to beneficiaries that talks about health plans/M+COs is marketing and health screening is a prohibited marketing activity.

The *Medicare and You Handbook* or *Medicare Compare Information* (from HCFA's website, www.medicare.gov), may be distributed by providers/provider groups without additional approvals. There may be other documents that provide comparative/descriptive material about health plans, are of a broad nature, and are written by either HCFA or another outside entity such as a consumer advocacy group. For guidance on whether this may be distributed without additional approvals, please contact the appropriate HCFA Regional Office. Please advise your health plan/M+CO providers and provider groups of the provisions of these rules.

Section 3 -- Answers to Frequently Asked Questions About Promotional Activities

1) **Q** We purchased books on health maintenance that we plan to give away to anyone attending one of our marketing presentations, regardless of whether or not they enroll in our health plan/M+CO. Because we purchased a large number of these books, we were able to buy them at a cost of $9.99 per book. However, on the inside jacket, the retail price is shown as $19.99. May we give these books away at our marketing presentation?

   A No. The retail purchase price of the book is $19.99, which exceeds HCFA's definition of nominal value.

2) **Q** We are participating in a health fair during which we will have marketing staff present. During the fair, we will offer a number of free health screening tests to people who attend. The value of these tests, if purchased, would be considerably more than $10. Is this permissible?

   A No. You may not offer these free tests because their value exceeds HCFA's definition of nominal value.

3) **Q** At our health plan/M+CO, we offer gifts of nominal value to people who call for more information. We then offer additional gifts if they come to marketing events. Each of the gifts meets HCFA's definition of nominal value, but taken together, the gifts are more than nominal value. Is this permissible?

   A Yes.

4) **Q** Listed below are some possible promotional items to encourage people to attend marketing presentations. Are these types of promotions permissible?

- Meals
- Day trips
- Magazine subscriptions
- Event tickets
- Coupon book (total value of discounts is less than $10)

A Yes. All these promotional items are permissible as long as they are offered to everyone who attends the event regardless of whether or not they enroll and as long as the gifts are $10 or less. Cash gifts are prohibited including charitable contributions made on behalf of people attending a marketing presentation and including gift certificates that can be readily converted to cash, regardless of dollar amount.

5) **Q** Can a health plan/M+CO advertise eligibility for a raffle or door prize of more than nominal value for those who attend a marketing presentation if the total value of the item is less than $10 per person attending?

A No. You cannot have a door prize of more than nominal value. Such gifts or prizes are prohibited by HCFA. However, the raffle or door prize can exceed the $10 limit if the M+CO is jointly sponsoring the prize with other health plans/M+COs at a health fair. See Section 1 of this Chapter for a discussion of rules pertaining to health fairs.

6) **Q** What about post-enrollment promotional activities? Are there any rules prohibiting such items or activities as coupon books, discounts, event tickets, day trips, or free meals to retain enrollees?

A Currently, the Medicare Managed Care Manual states that health plans/M+COs may not offer post-enrollment promotional items that in any way compensate beneficiaries for lower utilization of services. Any promotional activities or items offered by health plans/M+COs, including those that will be used to encourage retention of members, must be of nominal value, must be offered to all eligible members without discrimination, and must not be in the form of cash or other monetary rebates. The same rules that apply to pre-enrollment promotional activities apply to post-enrollment promotional activities.

7) **Q** Can health plans/M+COs provide incentives to current members to receive preventive care and comply with disease management protocols?

A Yes, as long as the incentives are: 1) offered to current members only; 2) not used in advertising, marketing, or promotion of the health plan/M+CO; 3) provided to promote the delivery of preventive care; and 4) are not cash or monetary rebates.

NOTE: **If** these products are in the HCFA-approved contracted health plan/M+CO benefit package (ACR and PBP) under "Preventive Services," the provision of such incentives are within the purview of the medical management philosophy of the M+CO and do not require

additional review by HCFA for marketing accuracy/compliance. The nominal value rule **does not** apply.

8) **Q** Can a health plan/M+CO offer reductions in premiums or enhanced benefits based on the length of a Medicare beneficiary's membership in the health plan/M+CO?

A No. Longevity of enrollment is not a basis for reductions in premium or enhanced benefits.[24]

9) **Q** Can a health plan/M+CO provide discounts to beneficiaries who prepay premiums for periods in excess of 1 month?

A No. Health plans/M+COs can not provide any discounts to Medicare beneficiaries for prepayment of premiums in excess of 1 month.

10) **Q** Can a health plan/M+CO take people to a casino or sponsor a bingo night at which the members earnings may exceed the $10 nominal value fee?

A No; the total value of the winnings may not exceed $10 and the winnings **cannot be in cash or an item that may be readily converted to cash.**

11) **Q** Can M+COs send a $1 lottery ticket as a gift to prospective members who request more information?

A Offering a $1 lottery ticket to prospective members violates the "no cash or equivalent" rule discussed above, whether or not the person actually wins since, generally, the "unscratched" ticket has a cash value of $1.

12) **Q** Can M+COs pay beneficiaries that sign up to be "ambassadors" a flat fee for transportation?

A If the M+CO employs a beneficiary to be an "ambassador" and travel reimbursement is part of the employment compensation, then HCFA has no oversight over this issue. If the beneficiary is not considered an employee, then the M+CO cannot pay the beneficiary, including reimbursement for transportation.

13) **Q** Can M+COs hold marketing presentations in clinics or hospitals?

A Yes, marketing presentations are allowed in clinics, hospitals or physicians offices (or other health care delivery locations) provided no patients being treated are invited or allowed to attend; and provided that the presentations are held in common areas (i.e., community or recreational rooms).

[24]This Ano@ statement also applies to Azero@ premium plans that might want to award a nominal value gift as a reward for longevity of enrollment.

14) **Q** Can M+COs that own nursing homes conduct health fairs and distribute enrollment forms to nursing home residents?

A Yes, M+COs that own nursing homes may conduct health fairs and distribute enrollment forms if the sales presentations are confined to a common area (i.e. community or recreational rooms) or if a member volunteered for an individual presentation. Promotional activities and sales presentations cannot be made in individual resident rooms without a prior appointment for a "home" visit. Such activities would be considered door-to-door solicitation and are prohibited. The M+CO is required to meet all health fair/sales presentation and enrollment requirements as currently outlined in the Marketing Guide and regulations.

15) **Q** What information should an active member be asked to release to a health plan/M+CO concerning a potential member lead?

A The health plan/M+CO can ask for referrals from active members, including names and addresses, but cannot request phone numbers. Health plans/M+COs can then use this information for soliciting by mail.

16) **Q** Can physician groups that contract with health plans/M+COs hire marketing firms to cold call from non-health plan/M+CO member listings?

A Yes, as long as the marketing guidelines for provider marketing are followed.

Section 4 -- Specific Guidance About Value-Added Items and Services

Value-Added Items and Services (VAIS) are items and services offered to M+C plan enrollees, by an M+CO, that do not meet the definition of "benefits" under the M+C program and may not be funded by Medicare program dollars. Nonetheless, VAIS may be of value to some beneficiaries, and we do not wish to deprive Medicare enrollees of access to items and services commonly available to commercial enrollees. Examples of VAIS may include, but are not limited to discounts in restaurants, stores, entertainment, and travel or discounts on health club memberships and on insurance policy premiums. HCFA permits VAIS to be offered to M+C enrollees under the rules outlined below.

From HCFA's perspective, VAIS are partly defined by what they are not -- they are <u>not</u> benefits under the M+C program. The M+C regulations at section 42 CFR 422.2 define benefits using a three-prong test:

1. Health care items or services that are intended to maintain or improve the health status of enrollees;

2. The M+C organization must incur a cost or liability directly related to the item or service and not just an administrative cost; and

3. The item or service is submitted and approved through the Adjusted Community Rate (ACR) benefit process.

All three parts of the definition must be met for an item or service to be considered a benefit under M+C. If an item or service fails to meet one or more of these parts, it is not a benefit; however, it may be offered to M+C enrollees as a VAIS, subject to the restrictions that follow.

The following examples demonstrate the application of the three-prong test:

Example 1:

An M+CO arranges for its enrollees a discount on all daily supplements purchased from a health food chain. The health food chain does not charge the M+CO for this discount, and requires the M+CO to develop a verification system so the health food chain can identify the organization's enrollees. The M+CO incurs an administrative cost to develop the verification system, but does not incur a cost of providing or furnishing the daily supplement. Therefore, the discount on daily supplements would be considered a VAIS. The ACR submitted by the M+CO should not reflect (as a Medicare enrollee benefit cost) the administrative cost of developing and providing the verification system.

Example 2:

An M+CO arranges for its enrollees a 10 percent discount on eyeglasses purchased from a group of eye doctors. The physician group charges the M+CO for the group's cost to administer the program, and requires the M+CO to develop a verification system to identify the organization's enrollees. The M+CO incurs two costs: 1) the M+CO pays the physician group's administrative cost of administering the program; and 2) the M+CO incurs the administrative cost for developing and providing the verification system. Both of these costs are administrative in nature, and the M+CO does not incur a cost of providing or furnishing the eyeglasses. Therefore, the discount on eyeglasses is considered a VAIS. The ACR submitted by the M+CO should not reflect (as a Medicare enrollee benefit cost) either of the two administrative costs.

Example 2a:

Given the same circumstances outlined in Example 2 above, except, the amount paid to the physician group actually subsidized the cost of the eyeglasses. In this case, the M+CO does incur a cost of providing or furnishing the eyeglasses. Therefore, the 10 percent discount on eyeglasses is not considered a VAIS. The ACR submitted by the M+CO should reflect the administrative costs it incurs and the amount paid to the physician group. The marketing materials should describe the eyeglass benefit with a 90 percent coinsurance. As with all benefits offered as part of an M+C plan, the Medicare enrollee must be afforded appeal rights for this benefit.

Restrictions on Value-Added Items and Services

M+COs may make VAIS available to Medicare enrollees in accordance with the following guidelines:

- VAIS must be offered uniformly to all M+C plan enrollees and potential enrollees.

- M+COs may not describe VAIS as benefits. In accordance with 42 CFR 422.80(e)(iv), which states that M+COs may not engage in activities that could mislead or confuse Medicare beneficiaries, the M+CO may not claim or imply that the VAIS are recommended by or endorsed by HCFA or Medicare.

- The M+CO may not use VAIS in an attempt to discourage enrollment or retention in M+C plans. Therefore, M+COs should not state or imply that enrollment in any plan is tied to a requirement to accept or purchase VAIS. As provided in 42 CFR 422.752(a)(4), M+COs may be subject to intermediate sanctions for engaging in any practice that could reasonably be expected to have the effect of denying or discouraging enrollment of individuals. See our discussion of plan descriptions and marketing materials below.

- The M+CO must maintain confidentiality of enrollee records in accordance with section 42 CFR 422.118 and other applicable statutes and regulations. The use or distribution of information about enrollees for non-plan purposes is prohibited. The M+CO is thus prohibited from circulating or selling names, addresses, or information about the characteristics of individual enrollees for purposes related to VAIS. Note however, that if the M+CO uses a third party to administer VAIS, the M+CO is ultimately responsible for adhering to and complying with confidentiality requirements.

Relation of Value-Added Items and Services to Benefits

Because VAIS do not meet the definition of a benefit under the M+C program, neither the actual costs of the VAIS nor associated administrative costs may appear in the ACR. Furthermore, because they are not contained within the contracted health benefits package, these services are not subject to the Medicare appeals process.

Similarly, VAIS may not appear in the Plan Benefit Package (PBP). VAIS may not be described in Medicare Compare, the *Medicare and You* handbook, or the Standardized Summary of Benefits (including in the M+CO special features section (Section 3) at the end).

All materials that describe the PBP must be approved in advance by HCFA (see section 42 CFR 422.80). This requirement does not apply to the content of descriptions of VAIS. **However, any description of VAIS must be preceded by the following prominently displayed language:**

- The products and services described on this page are neither offered nor guaranteed under the M+CO's contract with the Medicare program, but are made available to all enrollees

who are members of **[Name of M+CO]**.

- These products and services are not subject to the Medicare appeals process. Any disputes regarding these products and services may be subject to the **[Name of M+CO]** grievance process.

- Should a problem arise with any value-added item or service, please call **[Name of M+CO]** for assistance at **[M+CO customer service number]**. Our customer service hours are **[Enter hours]**.

Value-Added Items and Services Provided to Employer Groups

Value-added items and services may be offered to employer groups. Value-added items and services are offered outside the core benefit package, thus they are outside of HCFA's purview.

Application to Section 1876 Cost Plans

Value-added items and services may be offered by section 1876 cost plans. However, VAIS are non-covered services for which section 1876 cost plans are not reimbursed.

Section 5 -- Specific Guidance About the Use of Independent Insurance Agents

HCFA's previous policy of discouraging the use of independent agents and brokers for marketing purposes is hereby rescinded. HCFA recognizes that independent insurance agents can provide a necessary service to Medicare beneficiaries and potential enrollees. They can also be a valuable resource in helping to reach low-income and rural populations, persons with disabilities, and other special populations. Therefore, HCFA urges M+C organizations to consider requiring specific M+C training for their contracted agents. This will ensure that appropriate information is being delivered to Medicare beneficiaries and potential enrollees.

Please note that HCFA is aware that sales by independent insurance agents are typically tied to compensation and that agents are often given incentives to steer enrollees towards the carrier offering the most compensation. Further, independent insurance agents may be in a unique position to "cherry pick," given their often longstanding relationships with clients. Additional operational guidelines to address these concerns will be forthcoming.

Subject Matter Index (to be inserted)